

|                               |                  |              |
|-------------------------------|------------------|--------------|
| <b>Notice of Allowability</b> | Application No.  | Applicant(s) |
|                               | 09/673,794       | LARMA ET AL. |
|                               | Examiner         | Art Unit     |
|                               | Robert M. Joynes | 1615         |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to an Amendment and Response filed on November 11, 2003.
  2.  The allowed claim(s) is/are 1-17.
  3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
  4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a)  All    b)  Some\*    c)  None    of the:
      1.  Certified copies of the priority documents have been received.
      2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
    - (a)  The translation of the foreign language provisional application has been received.
  6.  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**
7.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  8.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1)  hereto or 2)  to Paper No. \_\_\_\_\_.
    - (b)  including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
    - (c)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).
9.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| <input type="checkbox"/> Notice of References Cited (PTO-892)   | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)          |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____.            |
| <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. _____  | <input type="checkbox"/> Examiner's Amendment/Comment                             |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
|   | <input type="checkbox"/> Other  |

  
**THURMAN K. PAGE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

***Allowable Subject Matter***

Claims 1-17 allowed.

The following is an examiner's statement of reasons for allowance: The prior art fails to teach or suggest a controlled release composition for the active agent levosimendan wherein the drug is release over an extended period of time. The prior art teaches controlled release composition for the drugs that are used to treat the same conditions levosimendan treats but the drugs are different in solubility properties. Therefore, the prior art cited cannot be used to show equivalency between the drugs compositions.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes  
Patent Examiner  
Art Unit 1615

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600